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FILED UNDER SEAL

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES ex rel, Darryl Copeland,	
	CIVIL ACTION NO. 06-CV-1630
	FILED UNDER SEAL
BRINGING THIS ACTION ON BEHALF OF HIMSELF AND THE UNITED STATES OF AMERICA	
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FILED
AUG 26 2010
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Plaintiffs/Relator,

v.

NOVARTIS PHARMACEUTICALS CORP.,

DEFENDANT.

AMENDED COMPLAINT

I. JURISDICTION AND VENUE

1. The jurisdiction of this court is invoked pursuant to 31 U.S.C. § 3730. This is a suit authorized and instituted pursuant to the *qui tam*

provisions of the "False Claims Act," as amended, 31 U.S.C. § 3729, et seq. Venue is proper under 31 U.S.C. § 3732(a).

2. Plaintiff, Darryl S. Copeland, qualifies as a *qui tam* relator in that, to the best of his information and belief, the allegations plaintiff makes in this Complaint have not been publicly disclosed. To the extent any public disclosures unknown to the plaintiff may have taken place, such publicly disclosed information does not form the basis of this suit, and plaintiff qualifies as an "original source" of said information. The facts averred herein are based on his personal observation and documents in his possession.

II. PARTIES

3. Plaintiff, Darryl S. Copeland, is an adult citizen of the United States and is a resident of Birmingham, Jefferson County, Alabama. Darryl S. Copeland was a current employee of Novartis Pharmaceutical Corporation at the time he filed suit.

4. The United States of America ("United States") has agents and representatives who are authorized under the "False Claims Act," as amended, 31 U.S.C. § 3729, et seq to proceed with this cause of action and who are located in Birmingham, Jefferson County, Alabama.

5. Defendant, Novartis Pharmaceutical Corporation, (hereinafter referred to as "NOVARTIS"), is a foreign corporation and does business and has employees and agents located in Birmingham, Jefferson County, Alabama, where many of the events giving rise to this lawsuit occurred. NOVARTIS is principally engaged in the manufacture and sale of pharmaceuticals including prescription pharmaceuticals falling under the jurisdiction and regulation of the U.S. Food and Drug Administration. At all times material hereto NOVARTIS regularly conducted substantial business in Alabama, maintained permanent employees and offices, and made and is making significant sales within Alabama, and is thus subject to personal jurisdiction in Alabama.

III. STATEMENT OF CLAIMS AGAINST NOVARTIS PHARMACEUTICAL

A. FACTS PERTAINING TO OXCARBAZEPHINE/TRILEPTAL

6. Plaintiff/ realtor, re-adopts and re-alleges paragraphs one (1) through five (5) as if fully set forth herein.

7. The relator has prepared, and will serve with this complaint, a disclosure pursuant to 31 U.S.C. § 3730(2) of information in his possession and of which he is the original source.

8. In 2000, NOVARTIS obtained approval from the U.S. Food and Drug Administration, (hereinafter the "FDA"), to market the prescription drug Oxcarbazephine. The FDA approved oxcarbazephine for use as an antiepiletic drug in adults, in dosages of 150, 300, 600 mg/5ml. NOVARTIS thereafter began marketing the drug under the brand name Trileptal. The FDA has not approved the use of Trileptal for any other purpose or in any other dosage. The FDA approved use of Trileptal represents a relatively narrow market, since it includes only persons suffering from seizures who are not fully responsive to the usual medications and who require additional medication. The FDA approved Trileptal for the use of monotherapy or adjunctive therapy in the treatment of partial seizures in adults with epilepsy and adjunctive therapy in the treatment of partial seizures in children four (4) to sixteen (16) with epilepsy.

9. Under applicable statutes and regulations, the manufacturer of a prescription drug regulated by the FDA may not promote or market the use of the drug for purposes or in dosages other than those approved by the FDA. Uses of a prescription drug for purposes other than those approved by the FDA are referred to as "off-label" uses. Promotion by a drug manufacturer of "off-label" uses of prescription drugs is strictly illegal

and contrary to the explicit policies and regulations of the United States Government.

10. After achieving FDA approval of Trileptal, NOVARTIS formed a scheme to increase the sales of Trileptal while avoiding the substantial expense and delay of petitioning the FDA for approval of expanded or additional uses of Trileptal. The scheme consisted of an elaborate and clandestine promotion of "off-label" uses of Trileptal, all in direct contravention of rules and regulations of the FDA and the Health Care Finance Agency, and in particular for the "off-label" uses of pain control, bi-polar, restless leg, monotherapy for seizures using extremely high dosages, attention deficit disorder, reflex-sympathetic dystrophy, post-herpetic neuropathy, diabetic neuropathy and other diseases and conditions.

11. This scheme was carried out by employing, among other things:

a. Illegal kickbacks to physicians in an effort to get them to prescribe large amounts of Trileptal for "off-label" purposes to patients whose prescriptions were paid for by medicare or medicaid;

b. The formation of a nationwide network of employees falsely referred to as "regional scientific directors" whose actual assigned duties consisted entirely of conventional direct sales and marketing activities and which did not include any legitimate scientific activity;

c. The illegal direct solicitation of physicians for "off-label" uses;

d. The making of false statements to physicians and pharmacists concerning the efficacy and safety of Trileptal for "off-label" uses;

e. The sale of Trileptal to the Veterans Administration for "off-label" uses;

12. NOVARTIS' sales of Trileptal are projected to exceed $200 million annually by the end of 2004. Approximately 50% of these sales are accounted for by "off-label" use of Trileptal. This rapid growth in "off-label" use of Trileptal is a direct result of NOVARTIS PHARMACEUTICAL'S illegal marketing activities. Of all of the "off-label" use of Trileptal, more than 50% is accounted for by patients whose prescriptions and paid for, directly or indirectly, by the United States, in the form of reimbursements

thru medicare and medicaid, and purchases by the Veterans Administration.

13. The "off-label" uses of Trileptal which are actively being promoted by NOVARTIS are uses which are not recognized as medically accepted uses by the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, or the American Medical Association Drug Evaluations, or by any peer-reviewed medical literature. Thus, these "off-label" uses are beyond the scope of uses designed by federal law and regulation, in particular 42 U.S.C. § 1396r-8, as eligible coverage by the medicare and medicaid programs.

14. There is no valid scientific evidence to support the contention that Trileptal is safe and effective for pain, for bi-polar disorder,for post-herpetic neuropathy, or for diabetic neuropathy. There is no valid scientific evidence concerning the therapeutic equivalence of Trileptal in any of these diseases.

B. FACTS PERTAINING TO DIOVAN

15. The relator has prepared, and will serve with this complaint, a disclosure pursuant to 31 U.S.C. § 3730(2) of information in his possession and of which he is an original source.

16. In 2000, NOVARTIS PHARMACEUTICAL obtained approval from the U.S. Food and Drug Administration, (hereinafter the "FDA"), to market the prescription drug Valsartan. The FDA approved Valsartan for use as a hypertension drug and for heart failure (NYHA class II-IV) in patients who are intolerant of angio tensin-converting enzyme inhibitors. NOVARTIS thereafter began marketing the drug under the brand name Diovan. The FDA has not approved the use of Diovan for any other purpose or in any other dosage. The FDA approved use of Diovan represents a relatively narrow market, since it includes only persons suffering from hypertension and heart failure (NYHA Class II-IV) in patients who are intolerant of angio tensin-converting enzyme inhibitors. The FDA approved Diovan for the use of the treatment of persons suffering from hypertension and heart failure (NYHA Class II-IV) in patients who are intolerant of angio tensin-converting enzyme inhibitors.

17. Under applicable statutes and regulations, the manufacturer of a prescription drug regulated by the FDA may not promote or market the use of the drug for purposes or in dosages other than those approved by the FDA. Uses of a prescription drug for purposes other than those approved by the FDA are referred to as "off-label" uses. Promotion by a

drug manufacturer of "off-label" uses of prescription drugs is strictly illegal and contrary to the explicit policies and regulations of the United States Government.

18. After achieving FDA approval of Diovan, NOVARTIS formed a scheme to increase the sales of Diovan while avoiding the substantial expense and delay of petitioning the FDA for approval of expanded or additional uses of Diovan. The scheme consisted of an elaborate and clandestine promotion of "off-label" uses of Diovan, all in direct contravention of rules and regulations of the FDA and the Health Care Finance Agency, and in particular for the "off-label" uses of preserving renal function in diabetics. Diovan has not been shown to be effective in any condition related to diabetes.

19. This scheme was carried out by employing, among other things:

a. Illegal kickbacks to physicians in an effort to get them to prescribe large amounts of Diovan for "off-label" purposes to patients whose prescriptions were paid for by medicare or medicaid;

b. The formation of a nationwide network of employees

falsely referred to as "regional scientific directors" whose actual assigned duties consisted entirely of conventional direct sales and marketing activities and which did not include any legitimate scientific activity;

c. The illegal direct solicitation of physicians for "off-label" uses;

d. The making of false statements to physicians and pharmacists concerning the efficacy and safety of Diovan for "off-label" uses;

e. The sale of Diovan to the Veterans Administration for "off-label" uses;

20. NOVARTIS' sales of Diovan are projected to exceed $200 million annually by the end of 2004. Approximately 50% of these sales are accounted for by "off-label" use of Diovan. This rapid growth in "off-label" use of Diovan is a direct result of NOVARTIS PHARMACEUTICAL'S illegal marketing activities. Of all of the "off-label" use of Diovan, more than 50% is accounted for by patients whose prescriptions and paid for, directly or indirectly, by the United States, in the form of reimbursements thru medicare and medicaid, and purchases by

the Veterans Administration.

21. The "off-label" uses of Diovan which are actively being promoted by NOVARTIS are uses which are not recognized as medically accepted uses by the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, or the American Medical Association Drug Evaluations, or by any peer-reviewed medical literature. Thus, these "off-label" uses are beyond the scope of uses designed by federal law and regulation, in particular 42 U.S.C. § 1396r-8, as eligible coverage by the medicare and medicaid programs.

22. There is no valid scientific evidence to support the contention that Diovan is safe and effective for preserving renal function in diabetes. There is no valid scientific evidence concerning the therapeutic equivalence of Diovan in any of these diseases.

C. FACTS PERTAINING TO ZELNORM

23. The relator has prepared, and will serve with this complaint, a disclosure pursuant to 31 U.S.C. § 3730(2) of information in his possession and of which he is the original source.

24. In 2003, NOVARTIS obtained approval from the U.S. Food and Drug Administration, (hereinafter the "FDA"), to market the prescription

drug Tegesarod Maleate. The FDA approved Tegesarod Maleate for use as an effective treatment for females with Irritable Bowl Syndrome when primary symptoms are abdominal pain, bloating and constipation. NOVARTIS thereafter began marketing the drug under the brand name Zelnorm. The FDA has not approved the use of Zelnorm for any other purpose or in any other dosage. The FDA approved use of Zelnorm represents a relatively narrow market, since it includes only the use of treatment of females when primary symptoms are irritable bowl syndrome with abdominal pain, bloating and constipation.

25. Under applicable statutes and regulations, the manufacturer of a prescription drug regulated by the FDA may not promote or market the use of the drug for purposes or in dosages other than those approved by the FDA. Uses of a prescription drug for purposes other than those approved by the FDA are referred to as "off-label" uses. Promotion by a drug manufacturer of "off-label" uses of prescription drugs is strictly illegal and contrary to the explicit policies and regulations of the United States Government.

26. After achieving FDA approval of Zelnorm, NOVARTIS formed a scheme to increase the sales of Zelnorm while avoiding the substantial

expense and delay of petitioning the FDA for approval of expanded or additional uses of Zelnorm. The scheme consisted of an elaborate and clandestine promotion of "off-label" uses of Zelnorm, all in direct contravention of rules and regulations of the FDA and the Health Care Finance Agency, and in particular for the "off-label" uses of diabetic gastroparesis and males with constipation.

27. This scheme was carried out by employing, among other things:

a. Illegal kickbacks to physicians in an effort to get them to prescribe large amounts of Zelnorm for "off-label" purposes to patients whose prescriptions were paid for by medicare or medicaid;

b. The formation of a nationwide network of employees falsely referred to as "regional scientific directors" whose actual assigned duties consisted entirely of conventional direct sales and marketing activities and which did not include any legitimate scientific activity;

c. The illegal direct solicitation of physicians for "off-label" uses;

d. The making of false statements to physicians and pharmacists concerning the efficacy and safety of Zelnorm for "off-label" uses;

e. The sale of Zelnorm to the Veterans Administration for "off-label" uses;

28. NOVARTIS' sales of Zelnorm are projected to exceed $150 million annually by the end of 2004. Approximately 50% of these sales are accounted for by "off-label" use of Zelnorm. This rapid growth in "off-label" use of Zelnorm is a direct result of NOVARTIS' illegal marketing activities. Of all of the "off-label" use of Zelnorm, more than 50% is accounted for by patients whose prescriptions and paid for, directly or indirectly, by the United States, in the form of reimbursements thru medicare and medicaid, and purchases by the Veterans Administration.

29. The "off-label" uses of Zelnorm which are actively being promoted by NOVARTIS are uses which are not recognized as medically accepted uses by the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, or the American Medical Association Drug Evaluations, or by any peer-reviewed medical literature. Thus, these "off-label" uses are beyond the scope of

uses designed by federal law and regulation, in particular 42 U.S.C. § 1396r-8, as eligible coverage by the medicare and medicaid programs.

30. There is no valid scientific evidence to support the contention that Zelnorm is safe and effective for diabetic gastroparesis or the treatment of constipation in male patients. There is no valid scientific evidence concerning the therapeutic equivalence of Zelnorm in any of these diseases or conditions.

D. FACTS PERTAINING TO SANDOSTATIN

31. The relator has prepared, and will serve with this complaint, a disclosure pursuant to 31 U.S.C. § 3730(2) of information in his possession and of which he is the original source.

32. In 1988, NOVARTIS obtained approval from the U.S. Food and Drug Administration, (hereinafter the "FDA"), to market the prescription drug Octreotide Acetate. The FDA approved Octreotide Acetate for use as an effective treatment for severe diarrhea and other symptoms that occur with certain cancers of the intestine. NOVARTIS thereafter began marketing the drug under the brand name Sandostatin. The FDA has not approved the use of Sandostatin for any other purpose or in any other dosage. The FDA approved use of Sandostatin represents a relatively

narrow market, since it includes only the use of treatment of patients with severe diarrhea and other symptoms that occur with certain cancers of the intestine.

33. Under applicable statutes and regulations, the manufacturer of a prescription drug regulated by the FDA may not promote or market the use of the drug for purposes or in dosages other than those approved by the FDA. Uses of a prescription drug for purposes other than those approved by the FDA are referred to as "off-label" uses. Promotion by a drug manufacturer of "off-label" uses of prescription drugs is strictly illegal and contrary to the explicit policies and regulations of the United States Government.

34. After achieving FDA approval of Sandostatin, NOVARTIS formed a scheme to increase the sales of Sandostatin while avoiding the substantial expense and delay of petitioning the FDA for approval of expanded or additional uses of Sandostatin. The scheme consisted of an elaborate and clandestine promotion of "off-label" uses of Zelnorm, all in direct contravention of rules and regulations of the FDA and the Health Care Finance Agency.

35. This scheme was carried out by employing, among other

things:

a. Illegal kickbacks to physicians in an effort to get them to prescribe large amounts of Sandostatin for "off-label" purposes to patients whose prescriptions were paid for by medicare or medicaid;

b. The formation of a nationwide network of employees falsely referred to as "regional scientific directors" whose actual assigned duties consisted entirely of conventional direct sales and marketing activities and which did not include any legitimate scientific activity;

c. The illegal direct solicitation of physicians for "off-label" uses;

d. The making of false statements to physicians and pharmacists concerning the efficacy and safety of Sandostatin for "off-label" uses;

e. Offering products and sales information to help employees sale and market Sandostatin for "off-label" use.

36. NOVARTIS' sales of Sandostatin have substantially increased

due to the "off-label" sale and promotion of Sandostatin. Approximately 50% of these sales are accounted for by "off-label" use of Sandostatin. This rapid growth in "off-label" use of Sandostatin is a direct result of NOVARTIS' illegal marketing activities.

37. The "off-label" uses of Sandostatin which are actively being promoted by NOVARTIS are uses which are not recognized as medically accepted uses by the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, or the American Medical Association Drug Evaluations, or by any peer-reviewed medical literature. Thus, these "off-label" uses are beyond the scope of uses designed by federal law and regulation, in particular 42 U.S.C. § 1396r-8, as eligible coverage by the medicare and medicaid programs.

38. There is no valid scientific evidence to support the contention that Sandostatin is safe and effective for Short Bowel Syndrome, Dumping Syndrome, CTID, HCC, Chronic Pancreatitis, EVB Prophylaxis, Cushings Syndrome, Ovarian Cancer, Thyroid Cancer, Breast Cancer, Cirhosis, Hepatorenal Syndrome, HIV/AID's, Autoimmune Insufficiency, Lupus, Gastrinoma, Hyperinsulinism, Glucaganoma, Graves Opthalmolpathy, Diabetic Diarrhea, Diarrhea After Surgery, Diarrhea Unspecified, IBS,

Abdominal Pain, Colitis and GI Blead. There is no valid scientific evidence concerning the therapeutic equivalence of Sandostatin in any of these diseases or conditions.

COUNT ONE
DIRECT SALES OF TRILEPTAL TO VETERANS ADMINISTRATION

39. Plaintiff/relator re-adopts and re-alleges paragraphs one (1) through thirty-eight (38) as if fully set forth herein.

40. NOVARTIS has sold, and is selling, significant quantities of Trileptal to the Veterans Administration for off-label use.

41. NOVARTIS is conducting, and has conducted, illegal direct promotion of off-label uses of Trileptal directly to the Veterans Administration. NOVARTIS has a special sales division assigned to the Veterans Administration. NOVARTIS' sales to the Veterans Administration have been derived through a pattern of fraud, to wit, the deliberate violation of the laws and regulations of the United states and the deliberate active concealment of those violations. NOVARTIS' deliberate violation of federal law used as a method of procuring sales of drugs to an agency of the federal government constituted a False Claim within the meaning of 31 U.S.C. § 3729. These claims of safety and efficacy for off-label uses are false and made with reckless disregard of the truth.

NOVARTIS' use of false statements concerning the safety and efficacy of Trileptal used as a means of procuring sales to the Veterans Administration constituted False Claims within the meaning of 31 U.S.C. § 3729.

COUNT TWO
DIRECT SALES OF DIOVAN TO VETERANS ADMINISTRATION

42. NOVARTIS has sold, and is selling, significant quantities of Diovan to the Veterans Administration for off-label use.

43. NOVARTIS is conducting, and has conducted, illegal direct promotion of off-label uses of Diovan directly to the Veterans Administration. NOVARTIS has a special sales division assigned to the Veterans Administration. NOVARTIS' sales to the Veterans Administration have been derived through a pattern of fraud, to wit, the deliberate violation of the laws and regulations of the United states and the deliberate active concealment of those violations. NOVARTIS' deliberate violation of federal law used as a method of procuring sales of drugs to an agency of the federal government constituted a False Claim within the meaning of 31 U.S.C. § 3729. These claims of safety and efficacy for off-label uses are false and made with reckless disregard of the truth. NOVARTIS' use of false statements concerning the safety and efficacy of

Diovan used as a means of procuring sales to the Veterans Administration constituted False Claims within the meaning of 31 U.S.C. § 3729.

COUNT THREE
DIRECT SALES OF ZELNORM TO VETERANS ADMINISTRATION

44. NOVARTIS has sold, and is selling, significant quantities of Zelnorm to the Veterans Administration for off-label use.

45. NOVARTIS is conducting, and has conducted, illegal direct promotion of off-label uses of Zelnorm directly to the Veterans Administration. NOVARTIS has a special sales division assigned to the Veterans Administration. NOVARTIS' sales to the Veterans Administration have been derived through a pattern of fraud, to wit, the deliberate violation of the laws and regulations of the United states and the deliberate active concealment of those violations. NOVARTIS' deliberate violation of federal law used as a method of procuring sales of drugs to an agency of the federal government constituted a False Claim within the meaning of 31 U.S.C. § 3729. These claims of safety and efficacy for off-label uses are false and made with reckless disregard of the truth. NOVARTIS' use of false statements concerning the safety and efficacy of Zelnorm used as a means of procuring sales to the Veterans Administration constituted False Claims within the meaning of 31 U.S.C. §

3729.

COUNT FOUR
ILLEGAL KICKBACKS REGARDING THE SALE OF TRILEPTAL

46. Federal laws and regulations governing the medicare and medicaid programs prohibit "kick-backs" to physicians and medical care providers, in particular 42 U.S.C. § 1320a-7 and 42 C.F.R. § 1001. "Kick-backs" have been defined as including payments, gratuities, and other benefits paid to physicians who prescribe prescription drugs by the manufacturers of the drugs.

47. As part of its nationwide program of off-label promotion of , NOVARTIS has established a system of "kick-backs" to physicians who are prescribers of large amounts of Trileptal. These "kick-backs" are disguised as consultantships although unrelated to any scientific or educational activity. The "kick-backs" have taken the form of travel benefits, entertainment, baseball tickets, NFL football tickets and other benefits. NOVARTIS has established formal internal guidelines for the award of these benefits to physicians which are based entirely in the amount of prescriptions written by the physicians and the ability of the physician to influence other physicians to begin prescribing Trileptal for off-label uses.

48. These "kick-backs" are strictly illegal and have had the effect

of greatly increasing the amount of Trileptal prescriptions, and indirectly the amount of money spent by the federal government for reimbursement of prescriptions covered by medicare. The payment of these kick-backs represents the inducement of federal payments through a pattern of fraudulent conduct, and constitute False Claims within the meaning of 31 U.S.C. § 3729.

COUNT FIVE
ILLEGAL KICKBACKS REGARDING THE SALE OF DIOVAN

49. Federal laws and regulations governing the medicare and medicaid programs prohibit "kick-backs" to physicians and medical care providers, in particular 42 U.S.C. § 1320a-7 and 42 C.F.R. § 1001. "Kick-backs" have been defined as including payments, gratuities, and other benefits paid to physicians who prescribe prescription drugs by the manufacturers of the drugs.

50. As part of its nationwide program of off-label promotion of Diovan, NOVARTIS has established a system of "kick-backs" to physicians who are prescribers of large amounts of Diovan. These "kick-backs" are disguised as consultantships although unrelated to any scientific or educational activity. The "kick-backs" have taken the form of cash payments and other benefits. NOVARTIS has established formal

internal guidelines for the award of these benefits to physicians which are based entirely in the amount of prescriptions written by the physicians and the ability of the physician to influence other physicians to begin prescribing Diovan for off-label uses.

51. These "kick-backs" are strictly illegal and have had the effect of greatly increasing the amount of Diovan prescriptions, and indirectly the amount of money spent by the federal government for reimbursement of prescriptions covered by medicare. The payment of these "kick-backs" represents the inducement of federal payments through a pattern of fraudulent conduct, and constitute False Claims within the meaning of 31 U.S.C. § 3729.

COUNT SIX
ILLEGAL KICKBACKS REGARDING THE SALE OF ZELNORM

52. Federal laws and regulations governing the medicare and medicaid programs prohibit "kick-backs" to physicians and medical care providers, in particular 42 U.S.C. § 1320a-7 and 42 C.F.R. § 1001. "Kick-backs" have been defined as including payments, gratuities, and other benefits paid to physicians who prescribe prescription drugs by the manufacturers of the drugs.

53. As part of its nationwide program of off-label promotion of

Zelnorm, NOVARTIS has established a system of "kick-backs" to physicians who are prescribers of large amounts of Zelnorm. These "kick-backs" are disguised as consultantships although unrelated to any scientific or educational activity. The "kick-backs" have taken the form of travel benefits, entertainment and other benefits. NOVARTIS has established formal internal guidelines for the award of these benefits to physicians which are based entirely in the amount of prescriptions written by the physicians and the ability of the physician to influence other physicians to begin prescribing Zelnorm for off-label uses.

54. These "kick-backs" are strictly illegal and have had the effect of greatly increasing the amount of Zelnorm prescriptions, and indirectly the amount of money spent by the federal government for reimbursement of prescriptions covered by medicare. The payment of these kick-backs represents the inducement of federal payments through a pattern of fraudulent conduct, and constitute False Claims within the meaning of 31 U.S.C. § 3729.

COUNT SEVEN
ILLEGAL KICKBACKS REGARDING THE SALE OF SANDOSTATIN

55. Federal laws and regulations governing the medicare and medicaid programs prohibit "kick-backs" to physicians and medical care

providers, in particular 42 U.S.C. § 1320a-7 and 42 C.F.R. § 1001. "Kick-backs" have been defined as including payments, gratuities, and other benefits paid to physicians who prescribe prescription drugs by the manufacturers of the drugs.

56. As part of its nationwide program of off-label promotion of Sandostatin, NOVARTIS has established a system of "kick-backs" to physicians who are prescribers of large amounts of Sandostatin. These "kick-backs" are disguised as consultantships although unrelated to any scientific or educational activity. The "kick-backs" have taken the form of travel benefits, entertainment and other benefits. NOVARTIS has established formal internal guidelines for the award of these benefits to physicians which are based entirely in the amount of prescriptions written by the physicians and the ability of the physician to influence other physicians to begin prescribing Sandostatin for off-label uses.

57. These "kick-backs" are strictly illegal and have had the effect of greatly increasing the amount of Sandostatin prescriptions, and indirectly the amount of money spent by the federal government for reimbursement of prescriptions covered by medicare. The payment of these kick-backs represents the inducement of federal payments through a

pattern of fraudulent conduct, and constitute False Claims within the meaning of 31 U.S.C. § 3729.

The Federal and State False Claims Acts 58. As set forth below, several states have passed False Claims Act legislation, which in most instances closely tracks the Federal FCA: California False Claims Act, Cal. Gov t Code § 12650 *et seq.*, Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, §§ 1201 *et seq.*, District of Columbia Procurement Reform Amendment Act, D.C. Code §§ 2-308.13 *et seq.*, Florida False Claims Act, Fla. Stat. §§ 68.081 *et seq.*, Georgia State False Medicaid Claims Act, Official Code of Georgia Annotated, 49-4-168, *et seq.*, c. 413, Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*, Illinois Whistleblower Reward and Protection Act,740 Ill. Comp. Stat. § 175/1 *et seq.*, Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5, Louisiana Medical Assistance Programs Integrity Law, 46 La. Rev. Stat. c. 3, § 437.1 *et seq.*, Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, §§ 5A *et seq.*, Michigan Medicaid False Claims Act, MI ST Ch. 400, Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq*,, New Hampshire False Claims Act,

N.H. RSA §§ 167:61-b, *et seq.*, New Mexico Medicaid False Claims Act, 2004 New Mexico Laws Ch. 49 (H.B. 468), New Jersey False Claims Act supplementing Title 2A of the New Jersey Statutes and amending P.L. 1968 c.413, New York State False Claims Act: 2007 New York laws 58, section 39, article XIII, §189 *et seq.*, Oklahoma Medicaid False Claims Act 2007 OK ALS 137, codified in Title 63, section 5053.1, Rhode Island False Claims Act, Chapter 9-1.1-3 *et seq.*, Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*, Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code §§ 36.001 *et seq.*, Wisconsin False Claims for Medical Assistance Act 20.93 1(2) *et seq.*, and Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.*, Montana Code Annotated 2009 §17-8-403, The Minnesota False Claims Act, Minn.Stat. §15C.01 *et seq.,* General Assembly of North Carolina Session 2009 §1-607, The Colorado Medicaid False Claims Act §25.5-4-305, Maryland False Health Claims Act of 2010 Subtitle 6, Connecticut Code Section 17b-301b. These State False Claims Acts apply, *inter alia*, to the state portion of Medicaid fraud losses caused by false Medicaid claims to the jointly federal-state funded Medicaid program. Each of the statutes listed above contains qui tam provisions governing, *inter alia*, a relator's

right to claim a share of the State's recovery.

LEGAL CLAIMS FOR RELIEF

COUNT EIGHT
VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov t Code § 12651(a)(1)

59. Relator restates and realleges the allegations contained in Paragraphs 1-58 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

60. The California False Claims Act, Cal. Gov't Code § 1265 1(a)(1), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state. . .for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
>
> (1)Knowingly presents or causes to be presented to an officer or employee of the state . . . a false claim for payment or approval.

61. Defendants knowingly presented or caused to be presented to the California Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Cal. Gov t Code § 1265 1(a)(1).

62. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINE
VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov t Code § 12651(a)(2)

63. Relator restates and realleges the allegations contained in Paragraphs 1-62 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

64. The California False Claims Act, Cal. Gov t Code § 1265 1(a)(2), specifically provides:

(a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state... for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state... for a civil penalty of up to ten

thousand ($10,000) for each false claim:

(2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state . . .

65. Defendants knowingly made, used and/or caused to be made or used false records and statements to get false and fraudulent claims paid and approved by the California Medicaid program, in violation of Cal. Gov t Code § 1265 1(a)(2).

66. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TEN
VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov t Code §12651(a)(3)

67. Relator restates and realleges the allegations contained in Paragraphs 1-66 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

68. The California False Claims Act, Cal. Gov t Code § 1265 1(a)(3), specifically provides:

(a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the

state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state...for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:

(3) Conspires to defraud the state.., by getting a false claim allowed or paid by the state...

69. Defendants conspired to defraud the State of California by getting false and fraudulent claims allowed and paid, in violation of Cal. Gov t Code § 1265 1(a)(3).

70. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ELEVEN
VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov t Code §12651(a)(7)

71. Relator restates and realleges the allegations contained in Paragraphs 1-70 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

72. The California False Claims Act, Cal. Gov t Code § 1265 1(a)(7), specifically provides:

(a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state. . .for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:

(7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state....

73. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Cal. Gov t Code § 1265 1(a)(7).

74. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWELVE
VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, §1201(a)(1)

75. Relator restates and realleges the allegations contained

in Paragraphs 1-74 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

76. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(1), specifically provides, in part, that any person who:

(a)(1) Knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

77. Defendants knowingly presented or caused to be presented, directly and indirectly, to the Delaware Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Del. Code Ann. tit. 6, § 1201(a)(1).

78. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTEEN
VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING

ACT
Del. Code Ann. tit. 6, § 1201 (a)(2)

79. Relator restates and realleges the allegations contained in Paragraphs 1-78 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

80. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(2), specifically provides, in part, that any person who:

(a)(2) Knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

81. Defendants knowingly made, used and caused to be made and used, directly and indirectly, false records and statements to get false and fraudulent claims paid and approved by the State of Delaware, in violation of Del. Code Ann. tit. 6, § 120 1(a)(2).

82. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FOURTEEN
VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, §1201(a)(3)

83. Relator restates and realleges the allegations contained in Paragraphs 1-82 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

84. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(3), specifically provides, in part, that any person who:

(a)(3) Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

85. Defendants conspired to defraud the State of Delaware by getting false and fraudulent claims allowed and paid, in violation of Del. Code Ann. tit. 6, § 1201(a)(3).

86. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTEEN

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, §1201(a)(7)

87. Relator restates and realleges the allegations contained inParagraphs 1-86 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

88. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §1201(a)(7), specifically provides, in part, that any person who:

[illegible](a)(7) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, increase, or decrease an obligation to pay or transmit money to or from the government; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

89. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Del. Code Ann. tit. 6, § 120 1(a)(7).

90. The State of Delaware paid said claims and has

sustained damages because of these acts by the Defendants.

COUNT SIXTEEN
VIOLATIONS OF THE DISTRICT OF COLUMBIA
PROCUREMENT REFORM AMENDMENT ACT
D.C. Code § 2-308.14(a)(1)

91. Relator restates and realleges the allegations contained in Paragraphs 1-90 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

92. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(1), specifically provides, in part:

(a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval.

93. Defendants knowingly caused to be presented to the District of Columbia Medicaid program false and fraudulent claims for

payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of D.C. Code § 2-308. 14(a)(1).

94. The District of Columbia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVENTEEN
VIOLATIONS OF THE DISTRICT OF THE COLUMBIA PROCUREMENT REFORM AMENDMENT ACT
D.C. Code § 2-308.14(a)(2)

95. Relator restates and realleges the allegations contained in Paragraphs 1-94 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

96. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(2), specifically provides, in part:

(a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person: